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| APPLICATION NO.           | FILING DATE                      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|----------------------------------|----------------------|---------------------|------------------|
| 09/892,993                | 06/27/2001                       | Kelly R. Brown       | ETH-1567            | 3764             |
|                           | 7590 12/27/200<br>& ENGLISH, LLP | 6                    | EXAMINER            |                  |
| FOUR GATEW                | VAY CENTER                       |                      | FUBARA, BLESSING M  |                  |
| 100 MULBERI<br>NEWARK, NJ |                                  |                      | ART UNIT            | PAPER NUMBER     |
|                           |                                  |                      | 1618                |                  |
|                           |                                  |                      | <del></del>         |                  |
| SHORTENED STATUTOR        | Y PERIOD OF RESPONSE             | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MO                      | NTHS                             | 12/27/2006           | PAPER               |                  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.   | Applicant(s) |  |  |  |
|--|---|--------------|--|--|--|
|  | 09/892,993  | BROWN ET AL. |  |  |  |
| Office Action Summary  | Examiner  | Art Unit     |  |  |  |
| ·  | Blessing M. Fubara  | 1618         |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |              |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |
| Status   |   |              |  |  |  |
| <ul> <li>1) Responsive to communication(s) filed on 01 Ju</li> <li>2a) This action is FINAL. 2b) This</li> <li>3) Since this application is in condition for allowant closed in accordance with the practice under E</li> </ul>  | action is non-final.<br>ice except for formal matters, pro                    |              |  |  |  |
| Disposition of Claims  |   |              |  |  |  |
| 4) ☐ Claim(s) 26-32 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 26-32 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or   | vn from consideration.  |              |  |  |  |
| Application Papers   |   |              |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |   |              |  |  |  |
| Priority under 35 U.S.C. § 119   |   |              |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |              |  |  |  |
| Attachment(s)  |   |              |  |  |  |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te           |  |  |  |

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#### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 10/10/2006. Claims 26-29 and new claims 30-32 are pending.

Previous rejections and objections that are not reiterated herein are withdrawn.

Upon further review and consideration of the prior art, the claims 26-29 read on Vacanti. Hence, the pending claims are rejected as described below.

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 26-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Vacanti et al. (US 6,171,610).

Vacanti disclose method of repairing tissues damaged by disease or injury (column 1, lines 14 and 15); the support structure can be shaped as the structure to be repaired such as cartilaginous tissue, meniscus of the knee or elbow (column 2, lines 59-65; column 6, lines 52-

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59) or the support structure can be shaped as a cylinder for the repair of spinal cord injury (column 8, lines 51 and 52; column 13, lines 28-37); examples of support structures are sponges, foams, corals, rigid inorganic, ceramic, or metal structures having internal pores such a honeycomb structure made from titanium, a skeleton of fine struts, such as a mesh of thin interwoven polymer fibers, and a skeleton of thick struts, such as a network of metal, inorganic, ceramic, or plastic rods (column 2, lines 14-58); the defective tissue can be removed to create a cavity where healthy tissue can grow from or cavity for receiving the support structure (column 3, lines 30-40; column 8, lines 39-50; column 15, lines 42-44; column 17, lines 49-53); and removal of defective tissue of surgically removing injured tissue read of boring at the area of defective tissue. Vacanti meets the limitations of the claims.

#### Response to Arguments

3. Applicant's arguments filed 5/02/06 have been fully considered but they are not persuasive.

Applicant argues that Vacanti does not specifically disclose the presence of specific interaction between a polymer phase and a ceramic phase; that Vacanti does not disclose an interphase region where the polymer phase is at least partially infused into the ceramic phase so that the ceramic phase is mechanically interlocked with the polymer phase.

### Response:

When the hydrogel, which is polymeric is brought into contact with the ceramic structure, an interaction is established between the ceramic phase structure and the hydrogel and the porous nature of the structure permits interpenetration of the hydrogel with the pores and then some interlocking mechanism is inherently established. Furthermore, there rejoin between the

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hydrogel phase and the ceramic phase is akin a region where the hydrogel and the ceramic phases are communicating.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al. (US 6,171,610) in view of Wise et al. (US 5,456,917)

Vacanti is discussed above. Vacanti does not disclose lyophilization step in the formation of foam. However, it is known in the art that foamed structures can be formed by lyophilization. For example Wise discloses foaming with lyophilization (column 7, lines 41-45; teaching reference). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form foamed structure by lyophilization.

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Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594.

The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara Aftubium Patent Examiner

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